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September 12, 2018

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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Centers for Disease Control and
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Atlanta, GA 30329

Patrick Breysse, Ph.D., CIH
Director
Agency for Toxic Substances and
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Center for Disease Control
200 Independence Ave., S.W.
Washington, DC 20201

Re: Request for Coordinated Nationwide PFAS Health Studies – Comments on Agency for Toxic Substance and Disease Registry Proposed Data Collection Plans (Docket Nos. ATSDR-2018-0002 and ATSDR-2018-0008)

Gentlemen:

Over one year ago, we wrote to the Agency for Toxic Substance and Disease Registry ("ATSDR") requesting that the Agency move forward immediately with a coordinated, comprehensive nationwide study and investigation of the human health impacts of exposures to highly fluorinated chemicals (per- and polyfluoroalkyl substances), collectively referred to as "PFAS." We asked that the Agency include within the scope of that investigation, not only all the millions of people across this country exposed to PFAS in their daily drinking water, but those within the firefighting

and emergency response community exposed to PFAS through firefighting foams or possibly through gear that was treated with materials that may have been made through processes that used one or more PFAS materials. (*See* Exs. A-B). In our September 2017 correspondence, we pointed out that the Agency already had acknowledged that such a national study could generate important "scientific knowledge about the health effects of PFAS exposures, in particular, PFOS and PFHxS exposures," but also had acknowledged that the study would have to be designed to encompass a sufficiently large population of exposed people in order to properly and thoroughly analyze certain types of less common potential health impacts and generate "meaningful and credible results." (*See id.* (citing to ATSDR's May 23, 2017 draft "Feasibility Assessment for Epidemiological Studies at Pease International Tradeport" ("Pease FS")) (relevant excerpts attached at Ex. C.)[1]

More specifically, ATSDR already concluded in the Pease FS that it needed at least 350 exposed children and at least 1500 exposed adults in order to generate meaningful conclusions about even a small number of potential health impacts in a particular community, and would likely need far more than that to draw meaningful conclusions about all the rest of the potential health impacts, such as cancer and ulcerative colitis. (*Id.*) Thus, according to ATSDR, it would be "possible to evaluate some health-related endpoints if a sufficient number of children [at least 350] and adults [at least 1500] from the Pease population participate" but "[o]ther health-related endpoints would require larger numbers of exposed individuals and would require the inclusion of populations from other sites who were exposed." (*Id.* at 5.)

A few months after our letter, in November 2017, legislation was passed authorizing millions of dollars in funding for the Agency to move forward with a "study on the human health implications of ... (PFAS) contamination in drinking water ... and any other ... relevant exposure pathways," which also required the Agency to use data collected from people exposed to PFAS at "no less than 8 current or former domestic or military installations." (Ex. D.) In other words, ATSDR was told that its study should include enough people exposed to PFAS through "relevant pathways" at enough locations to be able to actually generate meaningful results for any of the potential health impacts of concern. In response, we offered to assist the Agency with designing a proper nationwide study for PFAS exposures, consistent with the mandates of this new legislation, and building upon the work of the C8 Science Panel, which studied PFOA exposures using data collected from tens of thousands of people. We also noted that firefighter exposures fall within the scope of "other relevant exposure pathways," and should be included within the scope of ATSDR's PFAS work.

Unfortunately, it now appears from a recent ATSDR data collection proposal to begin a "proof-of-concept" study model at Pease (the "Pease Model") that ATSDR may

[1] ATSDR later finalized the Pease FS in November 2017 but the provisions discussed herein did not change in any material sense.

be setting this study up in such a way that it can never actually generate the data ATSDR previously indicated it needs to properly assess and draw meaningful conclusions about PFAS human health impacts, particularly serious disease like cancer and ulcerative colitis, and will specifically *exclude* from the study any relevant firefighter exposure pathways. For the reasons set forth below, we request that the Agency reevaluate this approach before moving forward with its study.

First, contrary to ATSDR's statement in its recent Federal Register notice seeking public comment on the proposed Pease Model, (83 Fed. Reg. 43685-87 (Aug. 27, 2018)), the federal legislation authorizing ATSDR's PFAS work did not restrict the work to the investigation of PFAS health impacts resulting from only "drinking water exposures," but authorized ATSR to consider other relevant exposure pathways. As such, ATSDR's proposal to specifically exclude all people who ever worked as a firefighter should be revisited. Including firefighters would be consistent with ATSDR's own PFAS human data collection guidance. In a May 2017 "Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Exposure Assessment Technical Tools" guidance document, ATSDR noted that "higher exposure groups and other subgroups of interest" should be "adequately sampled" as part of any such PFAS community health data collection project, and even included questions about firefighting exposures in its proposed questionnaire for people who would be part of any such PFAS studies. (Ex. E at I-2 and I-3, IV-7 and IV-8.)

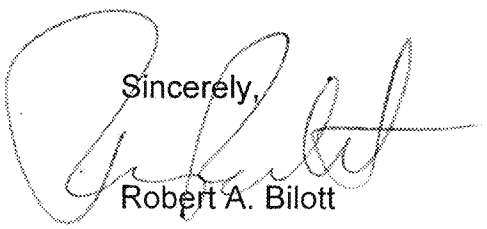
Second, it is not clear why ATSDR is now proposing to include fewer study participants than it previously said it needed to derive meaningful and credible conclusions on potential PFAS health impacts of interest. For example, ATSDR is now proposing to include 350 exposed children in the Pease Model, yet ATSDR previously stated that it would likely need more than 350 exposed children to adequately study the same thyroid function, neurobehavioral, sex hormone, immune function, and vaccine response endpoints that it plans to study now. (Ex. C at 3.) ATSDR also previously indicated that it would definitely need more than 350 exposed children to adequately study the thyroid disease and sexual maturation endpoints it plans to study now, or to study any childhood cancers. (*Id.*) Likewise, ATSDR is now proposing to include only 1000 exposed adults in the Pease Model, yet ATSDR previously indicated it would need at least 1500 exposed adults to adequately study any health endpoints in adults, and would likely need even more than 1500 to adequately study the liver function, thyroid function, thyroid disease, and endometriosis endpoints it plans to study now. (*Id.* at 4.) ATSDR also previously stated that it would definitely need more than 1500 exposed adults to adequately study the kidney disease, liver disease, and autoimmune disease endpoints it plans to study now, or to study any adult cancers or ulcerative colitis. (*Id.* at 5.) It is not clear why ATSDR is proposing to set up a study using fewer participants than it previously indicated it needed to derive "meaningful and credible results" on the endpoints to be studied. Proceeding with such an approach would seem certain to result in a report that cannot possibly generate data ATSDR believes it needs to confirm the connection between the PFAS exposures and the health endpoints at issue.

We respectfully request that ATSDR explain how the number of participants in the proposed Pease Model will be sufficient for ATSDR to actually confirm connections between the exposures at issue and the health endpoints being studied, given what ATSDR previously indicated on this point in the Pease FS. We also request that ATSDR clarify for the community that this proposed study will not be able to confirm or refute any potential cancer links, as the Agency is not even including any cancer outcomes within the scope of the study. In addition, we request that ATSDR explain how the data to be collected and results to be derived from the Pease Model will be used and/or incorporated within the scope of any nationwide PFAS study, given its prior statement that ATSDR's studies of individual PFAS exposure sites, such as Pease, "are not intended to yield information about PFAS exposures that will be generalized beyond the defined boundaries of each investigation," yet ATSDR intends to use such "findings to inform a future national PFAS health study." (83 Fed. Reg. 34137 (July 19, 2018).)

Does ATSDR intend to combine the data from the Pease study with data from other sites to generate a much larger pool of participants? Would these other sites be the 8 (or possibly as high as 15) unidentified "Exposure Assessment" ("EA") sites referenced in the Agency's July 19, 2018, Federal Register Notice? If so, how many total participants does ATSDR believe is necessary from all these sites, combined, to derive "meaningful and credible" conclusions as to links between PFAS exposures and each of the health endpoints of interest, including ulcerative colitis and cancer? If ATSDR moves forward with only the 8 confirmed EA sites, will the 3,032 total projected participants from each of those sites, combined, be sufficient according to ATSDR to draw "meaningful and credible" results as to all of the identified health endpoints of concern, including ulcerative colitis, thyroid disease, and cancer for all PFAS for the whole country? If ATSDR actually includes up to 15 EA sites, and includes the projected 5,685 total participants, would that number be sufficient according to ATSDR to derive meaningful and credible results for the whole country for each of these endpoints? When will the plans and protocol for such a national study be available for public comment?

Thank you.

Sincerely,



Robert A. Bilott

RAB:
Encls. (Exs. A-E)

EXHIBIT A

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September 5, 2017

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Jeff Sessions, Esq.
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United States Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530-0001

Re: Request for Coordinated Nationwide PFAS Health Study and Testing and Notice of Intent to Sue

Ladies and Gentlemen:

Millions of people across the country have been exposed to highly fluorinated chemicals (per- and polyfluoralkyl substances, including PFOA and PFOS) collectively referred to as "PFAS," in their drinking water supplies. EPA acknowledged the risks posed by the entire family of PFAS in its "Long-Chain Perfluorinated Chemicals (PFCs) Action Plan," which was released over seven years ago, but has never been fully

implemented. (*See* Ex. A (excerpts).) EPA has, however, recently confirmed that at least one PFAS – PFOA – poses sufficient "potential adverse effects for the environment and human health based on its toxicity, mobility, and bioaccumulation potential" to support investigating and addressing its presence in drinking water under the federal Superfund law, codified in the Comprehensive Environmental Response and Liability Act of 1980, as amended, 42 U.S.C. § 9601 *et seq.* ("CERCLA"). (*See e.g.*, Ex. B (excerpts) at 9.) Through the authority granted to ATSDR under that same Superfund law, ATSDR has classified PFAS as a class of chemicals that meet the definition of "toxic substance" within the scope of ATSDR's purview.[1] Consequently, ATSDR has developed a draft toxicological profile for PFAS, issued various statements and guidance to impacted individuals and physicians dealing with certain PFAS exposures, and even agreed to partner with a handful of state or local entities investigating specific instances of specific types of PFAS drinking water contamination in specific communities. (*See e.g.*, Ex. C.) To date, however, ATSDR has not embarked on any coordinated, comprehensive nationwide study or investigation of the impacts on human health from the presence of the entire *class* of PFAS in drinking water, or associated testing of all such impacted individuals. We write to request that ATSDR move forward immediately with such a national study and testing.

As explained below, ATSDR has the clear power and authority to mandate a national study of PFAS health impacts and associated testing, has access to mechanisms to secure funding from responsible parties, and has a proven model to follow to implement such a study/testing. Based on our past decade of experience designing and overseeing a project to assess human health impacts from one such PFAS – PFOA – we stand ready to assist ATSDR in overseeing the design and implementation of a nationwide study and testing focusing on the entire class of PFAS chemicals through a program that could encompass and involve all affected parties, including PFAS manufacturers, PFAS users, impacted water supplies, impacted residents, and affected governmental entities/contractors and regulators, in a way that provides everyone with independent, credible scientific answers and certainty.

I. ATSDR Has The Authority To Require A National PFAS Health Study and Testing And Ability To Secure Full Funding For Such Work.

Under Section 104 of CERCLA, ATSDR shall "provide medical care and testing to exposed individuals, including but not limited to tissue sampling, chromosomal testing where appropriate, epidemiological studies, or any other assistance appropriate under the circumstances" in situations involving "public health emergencies caused or believed to be caused by exposure to toxic substances.". (42 U.S.C. § 9604(i)(1)(D).) This is a non-discretionary mandate. Thus, under this provision of CERCLA, ATSDR (which, as noted above, already has classified PFAS as a "toxic substance") is not only

[1] *See also* 42 U.S.C. § 9604(i)(18).

authorized to conduct epidemiological studies and testing in circumstances where there have been excessive PFAS exposures, but is required to do so.

EPA repeatedly has indicated that situations involving excessive levels of PFAS in drinking water qualify as public health emergencies mandating immediate alternate water supplies. For example, as early as 2002, EPA entered a consent order in which it found that levels of a PFAS (PFOA) exceeding the non-regulatory threshold used by EPA at that time presented a sufficient threat of "imminent and substantial endangerment" to warrant the provision "[a]s soon as practicable" of alternative drinking water to those exposed. (*See* Ex. D (excerpts).) EPA entered similar orders noting the threat of such "imminent and substantial endangerment" from excessive PFAS levels in drinking water, mandating immediate alternate drinking water supplies, after EPA adopted its first provisional health advisory guidelines for short-term exposures to two different PFAS materials (PFOA and PFOS) in 2009. (*See e.g.*, Ex. E (excerpts).) EPA reaffirmed this position as recently as January 2017 when it modified one of those same consent orders to require immediate clean water if levels of PFAS exceeded EPA's new long-term health advisory level of no more than 0.07 ppb for individual or combined levels of PFOA and PFOS. (*See* Ex. F.) EPA noted that these new, lower PFAS drinking water guidelines were based on EPA's review of "the best available peer-reviewed studies" indicating that exposure to these PFAS "may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breastfed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney) , liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), thyroid effects and other effects (e.g., cholesterol changes)." (Ex. G.)

ATSDR's actions to date confirm its recognition that studying PFAS contamination issues falls squarely within its broad authority. As recently as May 23 of this year, ATSDR released the results of its own assessment of whether an epidemiological study by the Agency of those exposed to PFAS contamination in their drinking water would be feasible. (Ex. H (excerpts).) ATSDR confirmed in the context of evaluating the feasibility of studying adverse health effects among the adults, children, and military personnel exposed to multiple PFAS compounds in drinking water at the Pease International Tradeport that undertaking such a study could generate important "scientific knowledge about the health effects of PFAS exposures, in particular, PFOS and PFHxS exposures," if the study could be designed to encompass a sufficiently large population of impacted people. (*Id.* at 2.) In order to properly and thoroughly study certain types of less common diseases (including cancer) associated with these PFAS exposures, ATSDR acknowledged that there would need to be far more than the couple hundred or even couple thousand anticipated study participants at that one site, which might be feasible if multiple sites were incorporated into the study. (*Id.* at 43.) ATSDR even listed over 100 sites identified to date across the country where PFOS and/or PFHxS have been confirmed to be present in drinking water at levels above EPA's reporting limit for the chemicals under EPA's Unregulated

Contaminant Monitoring Rule 3 ("UCMR-3"), which could provide the needed, larger pool of study participants. (*Id.* at Table A.1.)

II. A Proven Model Exists For Developing A National PFAS Health Study.

Settlement of a prior class action lawsuit in which we represented the plaintiff class resulted in the creation of an independent scientific panel that studied the effects of PFOA-contaminated drinking water among a class of approximately 70,000 people whose drinking water supplies in West Virginia and Ohio had been contaminated with quantifiable levels of the chemical (0.05 ppb at the time) attributable to releases from the Washington Works manufacturing plant then-owned by E. I. du Pont de Nemours & Company ("DuPont"). Through an innovative settlement with DuPont in that case (known as the "*Leach* Case"), we were able to secure sufficient funds to pay for: 1) blood testing of approximately 69,000 people through a "C8 Health Project"; 2) creation of a new "C8 Science Panel" of independent, world-class epidemiologists charged with confirming which diseases were linked to PFOA exposure among the class being studied; 3) the design and implementation by the C8 Science Panel of approximately a dozen extensive epidemiological studies and retrospective exposure modeling work, including class-wide studies of the exposed population; 4) provisions for immediate and long-term clean water/water filtration; and 5) medical monitoring/testing for all class members for each disease linked to their PFOA exposure. (*See* http://www.c8sciencepanel.org and http://C-8MedicalMonitoringProgram.com.) Through that settlement, we also were able to secure a binding agreement up front on how the results of the independent scientific work would be used in connection with future injury and compensation claims among the *Leach* Case class members, including the extent to which the independent scientific work would conclusively resolve issues of general causation as between the PFAS chemical at issue and the class member exposures. The settlement also included an agreement that all active litigation among the parties would be stayed and future filings barred (yet with all claims preserved and statutes of limitations tolled), pending the final outcome of the agreed scientific process.

The work of the C8 Science Panel (and the related C8 Health Project) under this prior class settlement involved only one PFAS compound (PFOA) and only one responsible party (DuPont). There is no reason, however, why this same model cannot be expanded to the current situation facing communities across the United States involving one or more (or a combination of) the other PFAS compounds in their drinking water, potentially attributable to the actions of multiple responsible parties. In fact, expanding the model to include multiple responsible parties and regulators provides the opportunity for creating a much bigger pool of funds and the opportunity to spread costs among a much bigger and more diverse group. Likewise, addressing the issue within the context of a national class provides the opportunity for the responsible parties to fashion common, global remedies that allow for uniform, consistent relief and treatment of impacted parties and greater financial, scientific, and regulatory certainty.

ATSDR already has acknowledged the significance and utility of the C8 Science Panel/C8 Health Project model and work for addressing health issues related to PFAS exposures. As noted by ATSDR in its May 23, 2017, draft feasibility assessment for studies at the Pease International Tradeport, the C8 Science Panel's/C8 Health Project's work, which focused on human impacts from PFOA contamination in drinking water, allows ATSDR to focus future PFAS studies on the effects from exposure to other PFAS compounds, such as PFOS and PFHxS, and the synergistic/combined effects of multiple PFAS compounds (including PFOA) being present in drinking water at the same time. (*See* Ex. H at 3.) In short, the C8 Science Panel and C8 Health Project work allows ATSDR to start from what is already known and addressed by the C8 Science Panel and C8 Health Project with respect to the adverse effects of PFOA, and direct its resources toward studying the effects of having one or more (or combination) of the other PFAS materials in drinking water.

III. Now Is The Time To Act.

It is imperative that ATSDR take action now to respond to this ongoing, imminent and substantial threat to the health of millions of Americans across this country. Every day, another community somewhere in the United States wakes up to news that one or more (or some combination) of an ever-expanding class of PFAS compounds (some being identified for the first time as even existing) are poisoning the drinking water that they and their families rely upon. Every day another community is being told not to drink its water or to immediately get on bottled water because the concentration of PFAS exceeds current EPA guidelines or other health benchmarks. Residents, water suppliers, local, state and national elected officials, governmental entities, NGOs, business leaders, scientists – all are demanding credible, scientific answers to exactly what this mix of PFAS compounds in the water will do to people over time– especially those who have had long term exposures over many years or may be in sensitive subpopulations, such as infants, the elderly, or the infirm. Recently, the leaders of the health departments in five states – New York, Michigan, Pennsylvania, New Hampshire, Vermont, and Alaska – all signed a joint letter specifically asking ATSDR to undertake a national PFAS health study. (Ex. I.) In the meantime, an ever-growing number of lawsuits are being filed by a variety of lawyers asserting a myriad of different claims and theories against multiple parties under varying state laws and standards.

ATSDR is uniquely endowed with the legal authority and ability to fashion a response that addresses this problem in a comprehensive, coordinated, national basis among all necessary parties. ATSDR also has the rare ability and power to require those deemed responsible for such PFAS contamination of the country's drinking water supplies, including any military or other governmental entities, to pay for and/or fund such work. (*See e.g.*, 42 U.S.C. §§ 9604(i)(5)(D), 9607(a)(4)(D).[2]) Given ATSDR's own recognition of the feasibility, importance, and need to study the effects of multiple PFAS

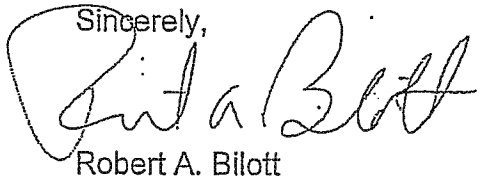
[2] *See also* 42 U.S.C §§ 9604(i)(17), 9620.

exposures in drinking water and its statutory authority and authorization to do so, ATSDR's continuing failure to do so provides a basis for a national class of all those negatively impacted by unstudied PFAS contamination of their drinking water supplies to bring a citizens' suit against ATSDR to force such action in the United States District Court for the District of Columbia, sixty days after ATSDR receives written notice of its failure to comply with this statutory mandate. (*See id.* § 9659.)

This letter serves as such a notice to ATSDR on behalf of our client, Dr. Arlo Paul Brooks, Jr., 92 Bella Vista Drive, Vienna, West Virginia . 26105 (304-481-2946), as a representative of a national class of all persons whose primary source of residential drinking water for at least one year or more has been found to contain one or more PFAS chemicals at a concentration above the Method Reporting Limit (MRL) for such PFAS chemical(s) established by EPA for purposes of UCMR-3, excluding any such water supply where the only PFAS found above such MRL is PFOA or is a water supply falling within the scope of the *Leach* Case settlement. ATSDR has identified in Table A1 to Exhibit H attached hereto over 100 such water supplies across the country meeting this definition, including the municipal water supply for Vienna, West Virginia, which Dr. Brooks has used as his primary source of residential drinking water for many years. (*See* Ex. H Table A1.)

Dr. Brooks was one of the founding partners of Brookmar – the entity that designed, managed, and implemented the highly successful C8 Health Project. Dr. Brooks stands ready to share his unparalleled experience with ATSDR to help the Agency move forward with the type of national PFAS study that is now required. We remain hopeful that this matter can be resolved within the next sixty days without the need for pursuing any citizens' suit. We are available to meet with you to discuss and fashion a Consent Order or other document that will allow the matter to be addressed and resolved in a coordinated, uniform manner among all impacted parties, using the prior C8 Science Panel/C8 Health Project and related settlement model.

Sincerely,



Robert A. Bilott

RAB:
Encls. (Exs. A-I)
Cc: Dr. A. Paul Brooks, Jr. (w/encls.)

EXHIBIT B

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Center for Disease Control
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Washington, DC 20201

Jeff Sessions, Esq.
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United States Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530-0001

Re: Request for Coordinated Nationwide PFAS Health Study and Testing and Notice of Intent to Sue

Ladies and Gentlemen:

For many years, unusually high rates of cancer and other adverse health effects have been observed among our nation's fire fighters and emergency responders (collectively "Responders"), particularly among Responders who handle or use firefighting foams made with highly fluorinated chemicals (per- and polyfluoralkyl substances, including PFOA and PFOS) collectively referred to as "PFAS," or wear gear

treated or made with such PFAS materials (collectively "PFAS Equipment"). EPA acknowledged the risks posed by the entire family of PFAS in its "Long-Chain Perfluorinated Chemicals (PFCs) Action Plan," which was released over seven years ago, but has never been fully implemented. (*See* Ex. A (excerpts).) EPA has, however, recently confirmed that at least one PFAS – PFOA – poses sufficient "potential adverse effects for the environment and human health based on its toxicity, mobility, and bioaccumulation potential" to support investigating and addressing its presence under the federal Superfund law codified in the Comprehensive Environmental Response and Liability Act of 1980, as amended, 42 U.S.C. § 9601 *et seq.* ("CERCLA"). (*See e.g.*, Ex. B (excerpts) at 9.) Through the authority granted to ATSDR under that same Superfund law, ATSDR has classified PFAS as a class of chemicals that meet the definition of "toxic substance" within the scope of ATSDR's purview.[1] Consequently, ATSDR has developed a draft toxicological profile for PFAS, issued various statements and guidance to impacted individuals and physicians dealing with certain PFAS exposures, and even agreed to partner with a handful of state or local entities investigating specific instances of specific types of PFAS contamination in specific communities. (*See e.g.*, Ex. C.) To date, however, ATSDR has not embarked on any coordinated, comprehensive nationwide study or investigation of the impacts on the health of Responders from their use and exposure to PFAS Equipment, or associated testing of all such impacted individuals. We write to request that ATSDR move forward immediately with such a national study and testing.

As explained below, ATSDR has the clear power and authority to mandate a national study of PFAS health impacts and associated testing among Responders exposed to PFAS Equipment, has access to mechanisms to secure funding from responsible parties, and has a proven model to follow to implement such a study/testing. Based on our past decade of experience designing and overseeing a project to assess human health impacts from one such PFAS – PFOA – we stand ready to assist ATSDR in overseeing the design and implementation of a nationwide study and testing focusing on Responder exposure to the entire class of PFAS chemicals through a program that could encompass and involve all affected parties, including manufacturers, impacted Responders, and affected governmental entities/contractors and regulators, in a way that provides everyone with independent, credible scientific answers and certainty.

I. ATSDR Has The Authority To Require A National PFAS Health Study and Testing And Ability To Secure Full Funding For Such Work.

Under Section 104 of CERCLA, ATSDR *shall* "provide medical care and testing to exposed individuals, including but not limited to tissue sampling, chromosomal testing where appropriate, epidemiological studies, or any other assistance appropriate under the circumstances" in situations involving "public health emergencies caused or believed to be caused by exposure to toxic substances." (42 U.S.C. § 9604(i)(1)(D).)

[1] *See also* 42 U.S.C. § 9604(i)(18).

This is a non-discretionary mandate. Thus, under this provision of CERCLA, ATSDR (which, as noted above, already has classified PFAS as a "toxic substance") is not only authorized to conduct epidemiological studies and testing in circumstances where there have been excessive PFAS exposures, but is required to do so.

EPA repeatedly has indicated that situations involving excessive levels of PFAS exposure qualify as public health emergencies mandating cessation of such exposures. For example, as early as 2002, EPA entered a consent order in which it found that levels of a PFAS (PFOA) exceeding the non-regulatory threshold used by EPA at that time presented a sufficient threat of "imminent and substantial endangerment" to warrant the provision "[a]s soon as practicable" of alternative drinking water to those exposed. (*See* Ex. D (excerpts).) EPA entered similar orders noting the threat of such "imminent and substantial endangerment" from excessive PFAS levels in drinking water, mandating immediate alternate drinking water supplies, after EPA adopted its first provisional health advisory guidelines for short-term exposures to two different PFAS materials (PFOA and PFOS) in 2009. (*See e.g.*, Ex. E (excerpts).) EPA reaffirmed this position as recently as January 2017 when it modified one of those same consent orders to require immediate clean water if levels of PFAS exceeded EPA's new long-term health advisory level of no more than 0.07 ppb for individual or combined levels of PFOA and PFOS. (*See* Ex. F.) EPA noted that these new, lower PFAS drinking water guidelines were based on EPA's review of "the best available peer-reviewed studies" indicating that exposure to these PFAS "may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breastfed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney) , liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), thyroid effects and other effects (e.g., cholesterol changes)." (Ex. G.)

ATSDR's actions to date confirm its recognition that studying PFAS contamination issues falls squarely within its broad authority. As recently as May 23 of this year, ATSDR released the results of its own assessment of whether an epidemiological study by the Agency of those exposed to PFAS contamination would be feasible. (Ex. H (excerpts).) ATSDR confirmed in the context of evaluating the feasibility of studying adverse health effects among the adults, children, and military personnel exposed to multiple PFAS compounds in drinking water at the Pease International Tradeport that undertaking such a study could generate important "scientific knowledge about the health effects of PFAS exposures, in particular, PFOS and PFHxS exposures," if the study could be designed to encompass a sufficiently large population of impacted people. (*Id.* at 2.) In order to properly and thoroughly study certain types of less common diseases (including cancer) associated with these PFAS exposures, ATSDR acknowledged that there would need to be far more than the couple hundred or even couple thousand anticipated study participants at that one site, which might be feasible if a much larger number of individuals was incorporated into the study. (*Id.* at 43.)

II. A Proven Model Exists For Developing A National PFAS Health Study.

Settlement of a prior class action lawsuit in which we represented the plaintiff class resulted in the creation of an independent scientific panel that studied the effects of PFOA-contaminated drinking water among a class of approximately 70,000 people whose drinking water supplies in West Virginia and Ohio had been contaminated with quantifiable levels of the chemical (0.05 ppb at the time) attributable to releases from the Washington Works manufacturing plant then-owned by E. I. du Pont de Nemours & Company ("DuPont"). Through an innovative settlement with DuPont in that case (known as the "*Leach* Case"), we were able to secure sufficient funds to pay for: 1) blood testing of approximately 69,000 people through a "C8 Health Project"; 2) creation of a new "C8 Science Panel" of independent, world-class epidemiologists charged with confirming which diseases were linked to PFOA exposure among the class being studied; 3) the design and implementation by the C8 Science Panel of approximately a dozen extensive epidemiological studies and retrospective exposure modeling work, including class-wide studies of the exposed population; 4) provisions for immediate and long-term clean water/water filtration; and 5) medical monitoring/testing for all class members for each disease linked to their PFOA exposure. (*See* http://www.c8sciencepanel.org and http://C-8MedicalMonitoringProgram.com.) Through that settlement, we also were able to secure a binding agreement up front on how the results of the independent scientific work would be used in connection with future injury and compensation claims among the *Leach* Case class members, including the extent to which the independent scientific work would conclusively resolve issues of general causation as between the PFAS chemical at issue and the class member exposures. The settlement also included an agreement that all active litigation among the parties would be stayed and future filings barred (yet with all claims preserved and statutes of limitations tolled), pending the final outcome of the agreed scientific process.

The work of the C8 Science Panel (and the related C8 Health Project) under this prior class settlement involved only one PFAS compound (PFOA) and only one responsible party (DuPont). There is no reason, however, why this same model cannot be expanded to the current situation facing Responders across the United States involving one or more (or a combination of) the other PFAS compounds in PFAS Equipment, potentially attributable to the actions of multiple responsible parties. In fact, expanding the model to include multiple responsible parties and regulators provides the opportunity for creating a much bigger pool of funds and the opportunity to spread costs among a much bigger and more diverse group. Likewise, addressing the issue within the context of a national class provides the opportunity for the responsible parties to fashion common, global remedies that allow for uniform, consistent relief and treatment of impacted parties and greater financial, scientific, and regulatory certainty.

ATSDR already has acknowledged the significance and utility of the C8 Science Panel/C8 Health Project model and work for addressing health issues related to PFAS exposures. As noted by ATSDR in its May 23, 2017, draft feasibility assessment for

studies at the Pease International Tradeport, the C8 Science Panel's/C8 Health Project's work, which focused on human impacts from PFOA contamination, allows ATSDR to focus future PFAS studies on the effects from exposure to other PFAS compounds, such as PFOS and PFHxS, and the synergistic/combined effects of being exposed to multiple PFAS compounds (including PFOA) at the same time. (*See* Ex. H at 3.) In short, the C8 Science Panel and C8 Health Project work allows ATSDR to start from what is already known and addressed by the C8 Science Panel and C8 Health Project with respect to the adverse effects of PFOA, and direct its resources toward studying the effects of Responders being exposed to one or more (or a combination) of the other PFAS materials through their use of PFAS Equipment.

III. Now Is The Time To Act.

It is imperative that ATSDR take action now to respond to this ongoing, imminent and substantial threat to the health of Responders across this country. Every day, more Responders are being diagnosed with cancer or other serious illnesses after working for years with PFAS-based firefighting foams or other PFAS Equipment. Every day Responders across the country are spraying PFAS-based foams or donning gear that was made or coated with PFAS materials. (*See e.g.* Ex. J.) Our nation's Responders deserve nothing less than immediate, credible, scientific answers to exactly what this mix of PFAS compounds in PFAS Equipment has done or will do to them. We already know that this particular group of Americans suffers from unusually high levels of serious disease, including multiple forms of cancer. (*See e.g.*, Ex. I (example health study excerpts).) They have a right to know whether the same equipment they relied upon to help save lives – the firefighting foam, fire-protection gear, and other PFAS Equipment – has put their own lives at risk for these terrible diseases.

ATSDR is uniquely endowed with the legal authority and ability to fashion a response that addresses this problem in a comprehensive, coordinated, national basis among all necessary parties. ATSDR also has the rare ability and power to require those deemed responsible for such harm, including any military or other governmental entities, to pay for and/or fund such work. (*See e.g.*, 42 U.S.C. §§ 9604(i)(5)(D), 9607(a)(4)(D).[2]) Given ATSDR's own recognition of the feasibility, importance, and need to study the effects of multiple PFAS exposures and its statutory authority and authorization to do so, ATSDR's continuing failure to do so provides a basis for a national class of all Responders who used PFAS Equipment to bring a citizens' suit against ATSDR to force such action in the United States District Court for the District of Columbia, sixty days after ATSDR receives written notice of its failure to comply with this statutory mandate. (*See id.* § 9659.)

This letter serves as such a notice to ATSDR on behalf of our client, Mr. John Jeffrey Hermes, 6441 Cottontail Trail, Burlington, Kentucky 41005 (859-689-2941), as a representative of a national class of all such Responders. Mr. Hermes is a prostate cancer survivor who has been a career Responder for over 25 years and has used

[2] *See also* 42 U.S.C §§ 9604(i)(17), 9620.

PFAS Equipment during most of that career, including PFAS-based firefighting foams and gear made and/or coated with PFAS chemicals.

We remain hopeful that this matter can be resolved within the next sixty days without the need for pursuing any citizens' suit. We are available to meet with you to discuss and fashion a Consent Order or other document that will allow the matter to be addressed and resolved in a coordinated, uniform manner among all impacted parties, using the prior C8 Science Panel/C8 Health Project and related settlement model.

Sincerely,

Robert A. Bilott

RAB:
Encls. (Exs. A-J)
Cc: Mr. John Jeffrey Hermes (w/encls.)

EXHIBIT C

Brief Overview of the Feasibility Assessment for Epidemiological Studies at Pease International Tradeport

May 23, 2017

1. Introduction

The Pease International Tradeport is located in Portsmouth, New Hampshire (NH) on land that was formerly the Pease Air Force Base. In 1993, companies began to operate at the Tradeport. It contains over 250 companies employing more than 9,525 people. Two day care centers are located at the Tradeport.

In April and May 2014, the three drinking water supply wells serving the Pease Tradeport were sampled for perfluoroalkyl substances (PFAS). The Haven Well, which supplied about half of the total drinking water at the Pease Tradeport at the time of the sampling, was found to have perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), and perfluorohexane sulfonate (PFHxS) levels averaging 2.5 micrograms per liter (µg/L), 0.34 µg/L, and 0.90 µg/L, respectively. While the Environmental Protection Agency has a lifetime health advisory for PFOS and PFOA, no regulatory standards by any federal agency have been promulgated for PFAS. Much lower levels of these contaminants were found in the other two wells serving the Pease Tradeport. The Haven well was shut down in May 2014.

The contamination of the drinking water wells was the result of the use of aqueous film forming foam (AFFF) at the former Pease Air Force Base for firefighting training and to extinguish flammable liquid fires. The firefighting foam contained PFAS. It was used at the base from approximately 1970 until the base closed in 1991. The AFFF likely leached into the soil and groundwater and migrated to the three drinking water supply wells that served the base and later served the Pease Tradeport. It is not known when these wells were contaminated with PFAS. However, it is possible that the contamination began when the base was still in operation and prior to the opening of the Tradeport in 1993.

During April – October 2015, a blood testing program for PFAS was conducted by the NH Department of Health and Human Services. The program was for those who may have been exposed to the contaminated drinking water at the Pease Tradeport or those who consumed water from contaminated private wells adjacent to the Tradeport. A total of 1,578 individuals volunteered to submit a blood sample. A report of the program found that the average levels of PFOS, PFOA and PFHxS in the blood of those tested were higher than national averages for these chemicals (http://www.dhhs.nh.gov/dphs/documents/pease-pfc-blood-testing.pdf).

The Agency for Toxic Substances and Disease Registry (ATSDR) evaluated the feasibility of conducting epidemiological studies of the populations at the Pease Tradeport. This assessment was in response to community health concerns and the community's request for health studies. The purpose of the assessment was to determine whether studies are feasible to conduct at Pease given the size of the exposed populations, and whether data exist to conduct scientifically credible studies.

2. Approach

ATSDR used three criteria to determine whether health studies were feasible:

- Meaningful and credible results – a study should have sufficient validity and precision, be capable of detecting moderate as well as large health-related effects, and be as responsive as possible to the community's questions and concerns.

- Scientific importance – a study should evaluate biologically plausible diseases and other health-related endpoints (also called "effect biomarkers") and improve our understanding of possible health effects of PFAS exposures.

- Public health significance – a study should provide a strong basis for determining if PFAS exposures increase the risks of specific adverse health effects, and if so, what public health actions are necessary to reduce the risks. The study should also be relevant to other populations with similar exposures.

Feasibility was also assessed in terms of whether sufficient participation (sample size) could be obtained from within the Pease community, or whether the study would need to be expanded to other communities beyond the Pease population.

ATSDR reviewed published health studies to identify health-related endpoints that have been studied and the data gaps that exist. The review found that most information on potential health effects concerned exposures to PFOA, much less information was available for PFOS exposures, and very little information was available for PFHxS exposures. In general, there was limited information on the human health effects of PFAS exposures because research is still at an early stage. Because of this research gap, health studies of the Pease population might contribute to scientific knowledge about the health effects of PFAS exposure, in particular, PFOS and PFHxS exposure.

Based on its review, ATSDR concluded that several health-related endpoints could be considered for studies of the Pease population. However, whether it is feasible to study a specific health-related endpoint depends to a great extent on the size of the exposed population that can be recruited into a study. In order to determine the size of the exposed population required to study each health-related endpoint effectively, sample size calculations were made.

3. Feasibility of Possible Studies at Pease

a. Feasibility of a Children's Health Study at Pease

To determine the population appropriate for a children's study at Pease, ATSDR took into account the date when the Haven well was shut down, the length of time (e.g., "half-life") that PFHxS and PFOS remain in the blood after exposure, and the age range appropriate for the health endpoints under consideration. ATSDR concluded that a study is feasible of children who attended a day care center at

Pease any time prior to June 2014 and who will be aged 4 – 16 years at the time the study begins. Because PFAS-contaminated drinking water exposures could occur to children in utero and during breastfeeding if the mother worked at the Pease Tradeport, the study would include these additional children if the exposures began prior to June 2014 and their ages are 4 – 16 years at the time the study begins.

The sample size calculations indicated that at least 350 exposed children were needed to be included in a study. The study would also require a comparison group of at least 175 children unexposed to the contaminated drinking water at the Pease Tradeport. Based on this sample size, health-related endpoints were grouped into three categories: 1) feasible to study, 2) possible to study in children at Pease (but likely will require recruiting a larger sample size than 350 exposed and 175 unexposed children from the Pease community), and 3) not feasible to study using the Pease children population unless additional populations from other communities exposed to PFAS-contaminated drinking water are included in the study.

<u>Health-related endpoints feasible to study in children at Pease</u>:

- Mean difference in lipids (total cholesterol, LDL, HDL, triglycerides)
- Mean difference in estimated glomerular filtration rate (eGFR), a measure of kidney function
- Insulin-like Growth Factor – 1 (a measure of growth hormone deficiency)
- Overweight/Obesity

<u>Health-related endpoints that may be possible to study in children at Pease</u> (although a larger sample size from the Pease community will likely be needed):

- Mean difference in uric acid
- Elevated total cholesterol (hypercholesterolemia)
- Elevated uric acid (hyperuricemia)
- IQ/neurobehavioral
- Thyroid function
- Sex hormones
- Asthma and atopic dermatitis (Immune function)
- Rhinitis (stuffy, runny nose)
- Antibody response to rubella, mumps and diphtheria vaccines

<u>Health-related endpoints not feasible to study using the Pease children population</u> (in order to address these health endpoints, populations from other sites beyond the Pease community with PFAS-contaminated drinking water would need to be included along with the Pease children population):

- Attention deficit/hyperactivity disorder (ADHD)
- Autism spectrum disorder
- Delayed puberty
- Thyroid disease
- Childhood cancers

b. Feasibility of an Adult Health Study at Pease

Based on the date when the Haven well was shut down and the length of time (e.g., "half-life") that PFHxS and PFOS remain in the blood after exposure, ATSDR concluded that an adult study at Pease of adults aged ≥18 years who worked anytime at the Pease Tradeport during January 2008 - May 2014 is feasible.

The sample size calculations indicated that at least 1,500 exposed adults needed to be included in a study. The study would also require a comparison group of at least 1,500 adults unexposed to the contaminated drinking water at the Pease Tradeport. Based on this sample size, health-related endpoints were grouped into three categories: 1) feasible to study, 2) possible to study at Pease (but likely will require recruiting a larger sample size than 1,500 exposed and 1,500 unexposed adults from the Pease community), and 3) not feasible to study using the Pease adult population unless additional populations from other communities exposed to PFAS-contaminated drinking water are included in the study.

<u>Health-related endpoints feasible to study at Pease</u>:

- Mean difference in lipids (total cholesterol, LDL, HDL, triglycerides)
- Elevated total cholesterol (hypercholesterolemia)
- Mean difference in uric acid
- Elevated uric acid (hyperuricemia)
- Thyroid disease (unconfirmed)
- Cardiovascular disease
- Hypertension
- Osteoarthritis and osteoporosis
- Mean differences in serum immunoglobin (IgA, IgE, IgG, IgM), and C-reactive protein (an indicator of inflammation); increase in antinuclear antibodies (an indicator of autoimmune reaction); alterations in specific cytokines

<u>Health-related endpoints that may be possible to study at Pease</u> (although a larger sample size from the Pease community may be needed):

- Liver function
- Thyroid disease (confirmed)
- Thyroid function
- Endometriosis
- Pregnancy-induced hypertension

Health-related endpoints not feasible to study using the Pease adult population (i.e., populations from other sites beyond the Pease community with PFAS-contaminated drinking water would need to be included to make the study feasible):

- Liver disease
- Kidney disease
- Ulcerative colitis
- Rheumatoid arthritis
- Lupus
- Multiple sclerosis
- Kidney cancer (and other adult cancers)

c. Study of former military service and civilian workers at the Pease Air Force Base

Based on sample size considerations, ATSDR concluded that it is not feasible to conduct a mortality or cancer incidence study that is limited to the military service and civilian workers who were stationed or worked at the Pease Air Force Base. Such studies would require, in addition to the Pease Air Force Base populations, several thousands of exposed populations from military bases where PFAS-contaminated drinking water occurred, as well as several thousands of comparison populations from military bases that did not have drinking water contamination.

4. Conclusions

The feasibility assessment concluded that it is possible to evaluate some health-related endpoints if a sufficient number of children and adults from the Pease population participate. Other health-related endpoints would require larger numbers of exposed individuals and would require the inclusion of populations from other sites who were exposed to PFAS-contaminated drinking water. The feasibility assessment concluded that a third study design, a mortality and cancer incidence study of former military service and civilian worker personnel, would not be feasible solely with the population at Pease.

No single study of the Pease population will provide clear answers to the community about whether their exposures to the PFAS-contaminated drinking water caused their health problems. All epidemiological studies of environmental exposures and health outcomes have limitations and uncertainties. Whether a study will find an association between an environmental exposure and health effects cannot be known prior to conducting the study. The ability of a study of the Pease population to provide useful information will depend to a great extent on the success of recruiting sufficient number of study participants.

The feasibility assessment is still a draft. It will be finalized once the Pease Community Assistance Panel (CAP) and the larger Pease Tradeport community have the opportunity to review and make comments on the assessment. ATSDR will then revise the assessment based on the comments received. The feasibility of successfully evaluating particular health-related endpoints (or effect biomarkers) could change depending on final study design and goals.

EXHIBIT D

115TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPORT
115–???

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2018

CONFERENCE REPORT

TO ACCOMPANY

H.R. 2810

NOVEMBER --, 2017.—Ordered to be printed

SEC. 315. DEPARTMENT OF THE ARMY CLEANUP AND REMOVAL OF PETROLEUM, OIL, AND LUBRICANT ASSOCIATED WITH THE PRINZ EUGEN.

(a) AUTHORITY.—Amounts authorized to be appropriated for the Department of the Army may by used for all necessary expenses for the removal and cleanup of petroleum, oil, and lubricants associated with the heavy cruiser Prinz Eugen, which was transferred from the United States to the Republic of the Marshall Islands in 1986.

(b) CERTIFICATION.—If the Secretary of the Army does not use the authority provided by subsection (a), the Secretary shall submit a certification to the congressional defense committees not later than September 30, 2018, that the petroleum, oil, and lubricants associated with the heavy cruiser Prinz Eugen do not adversely impact safety or military operations.

SEC. 316. CENTERS FOR DISEASE CONTROL STUDY ON HEALTH IMPLICATIONS OF PER- AND POLYFLUOROALKYL SUBSTANCES CONTAMINATION IN DRINKING WATER.

(a) STUDY ON HUMAN HEALTH IMPLICATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, and, as ap-

propriate, the National Institute of Environmental Health Sciences, and in consultation with the Department of Defense, shall—

(A) commence a study on the human health implications of per- and polyfluoroalkyl substances (PFAS) contamination in drinking water, ground water, and any other sources of water and relevant exposure pathways, including the cumulative human health implications of multiple types of PFAS contamination at levels above and below health advisory levels;

(B) not later than 5 years after the date of enactment of this Act (or 7 years after such date of enactment after providing notice to the appropriate congressional committees of the need for the delay)—

(i) complete such study and make any appropriate recommendations; and

(ii) submit a report to the appropriate congressional committees on the results of such study; and

(C) not later than one year after the date of the enactment of this Act, and annually thereafter until submission of the report under subparagraph (B)(ii), submit to the appropriate

congressional committees a report on the progress of the study.

(2) FUNDING.—Of the amounts authorized to be appropriated by this Act for the Department of Defense, $7,000,000 shall be available to carry out the study under this subsection.

(3) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this subsection, the term "appropriate congressional committees" means—

(A) the congressional defense committees;

(B) the Committee on Heath, Education, Labor, and Pensions, the Committee on Environment and Public Works, and the Committee on Veterans' Affairs of the Senate; and

(C) the Committee on Energy and Commerce and the Committee on Veterans' Affairs of the House of Representatives.

(b) EXPOSURE ASSESSMENT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, and, as appropriate, the National Institute of Environmental Health Sciences, and in consultation with the Department of Defense, shall conduct an exposure as-

sessment of no less than 8 current or former domestic military installations known to have PFAS contamination in drinking water, ground water, and any other sources of water and relevant exposure pathways.

(2) CONTENTS.—The exposure assessment required under this subsection shall—

(A) include—

(i) for each military installation covered under the exposure assessment, a statistical sample to be determined by the Secretary of Health and Human Services in consultation with the relevant State health departments; and

(ii) bio-monitoring for assessing the contamination described in paragraph (1); and

(B) produce findings, which shall be—

(i) used to help design the study described in subsection (a)(1)(A); and

(ii) released to the appropriate congressional committees not later than 1 year after the conclusion of such exposure assessment.

(3) TIMING.—The exposure assessment required under this subsection shall—

(A) begin not later than 180 days after the date of enactment of this Act; and

(B) conclude not later than 2 years after such date of enactment.

(c) COORDINATION WITH OTHER AGENCIES.—The Agency for Toxic Substance and Disease Registry may, as necessary, use staff and other resources from other Federal agencies in carrying out the study under subsection (a) and the assessment under subsection (b).

(d) NO EFFECT ON REGULATORY PROCESS.—The study and assessment conducted under this section shall not interfere with any regulatory processes of the Environmental Protection Agency, including determinations of maximum contaminant levels.

SEC. 317. SENTINEL LANDSCAPES PARTNERSHIP.

(a) ESTABLISHMENT.—The Secretary of Defense, in coordination with the Secretary of Agriculture and the Secretary of the Interior, may establish and carry out a program to preserve sentinel landscapes. The program shall be known as the "Sentinel Landscapes Partnership".

(b) DESIGNATION OF SENTINEL LANDSCAPES.—The Secretary of Defense, the Secretary of Agriculture, and the Secretary of the Interior, may, as the Secretaries de-

EXHIBIT E

Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Exposure Assessment Technical Tools

Centers for Disease Control and Prevention (CDC)
Agency for Toxic Substances and Disease Registry (ATSDR)

May 2017

Using Serum Testing as a Component for Assessing Exposure in Communities with Drinking Water Contaminated with Per- or Polyfluoroalkyl Substances (PFAS)

This framework document is designed to help state health departments when measuring and evaluating community exposures to per- or polyfluoroalkyl substances (PFAS) in drinking water.

In this framework, a statistically based approach to recruit, measure, and evaluate community exposures to PFAS includes:

- Biomonitoring (serum testing),
- Identifying exposure source(s), and
- Administering questionnaires to provide an assessment of exposure source(s) along with the magnitude and distribution of exposure in the community.

NOTE: This framework document does not assist in determining whether biomonitoring is appropriate or necessary. The decision to conduct biomonitoring should be based on specific circumstances of affected communities along with considerations related to human subjects' protections. Health departments need to consider that the approach described here will require identification of a funding source and specific staff expertise. CDC and ATSDR can provide technical assistance to health departments to help develop and execute a biomonitoring effort. Finally, this framework may not be applicable to all proposed biomonitoring efforts; that is, this framework should not preclude other approaches to biomonitoring.

Centers for Disease Control and Prevention (CDC)
Agency for Toxic Substances and Disease Registry (ATSDR)

May 2017

Introduction

CDC's National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR) work to protect communities from exposure to harmful chemicals.

PFAS have been detected in numerous public and private drinking water supplies throughout the United States. State and local health departments requested CDC and ATSDR's assistance on how to best assess exposure to PFAS in communities where PFAS contamination of water is known or reasonably expected.

CDC and ATSDR understand and acknowledge that individuals may want to know the level of PFAS in their blood. However, conducting biomonitoring on all individuals in a community may not be feasible. The statistically based, scientific approach outlined in this framework allows for a practical and feasible approach for assessing potential community exposures to PFAS and will provide estimated serum PFAS levels in the community members who were not tested. If the state health or other entity opts for an alternate approach, we suggest use of statistical participant selection/recruitment methods to ensure results can be generalized to the affected community.

8- Step Approach to Assess Community Exposures to PFAS[1,2]

CDC/ATSDR suggest the following approach to assess community exposure to PFAS from contaminated drinking water.

1) Evaluate existing data on PFAS in drinking water and assess potential current or past community exposure. Consider whether additional exposure pathway data are important (e.g., consumer products, dietary sources including fish from PFAS-contaminated water bodies, crops grown in fields amended with contaminated biosolids, and occupational exposure). ATSDR's Public Health Assessment Guidance Manual provides helpful information for evaluating existing data.

2) If PFAS was or is expected to be elevated in drinking water compared to EPA's Lifetime Health Advisory (HA) or state-specific threshold levels, identify variables expected to be associated with increased exposure within the population. Examples of variables can include people in a particular geographic area where elevated PFAS water concentrations existed in the past or currently exist, or people who have been drinking contaminated water over a long period of time, etc. Develop a protocol that describes how these factors will be assessed, and include provision of the variables in steps number 3 through 7 below.[2]

3) Develop and implement a communications plan.

4) Develop a questionnaire that includes demographics, geographic information, and factors influencing exposure to PFAS in water and other potential sources of PFAS. The CDC/ATSDR PFAS Environmental Assessment Technical Tools (PEATT) provide a questionnaire example with core questions.

5) Identify laboratories (with appropriate quality control assurance) capable of performing water PFAS measurements using EPA Method 537. Likewise, identify a quality laboratory to perform serum PFAS measurements. The PEATT provides serum sample collection, storage, and analysis information.

[1] A detailed description and approach is provided in the NCEH/ATSDR PFAS Environmental Assessment Technical Tools (PEATT) for PFAS evaluations:

[2] Human subjects' protection policies and procedures should be followed.

6) Develop a statistically based, community sampling design that will provide information about the range of PFAS exposures in an affected community. Ensure that higher exposure groups and other subgroups of interest are adequately sampled.[3]
    a) People likely to have higher exposure to PFAS
    b) Relevant demographic groups (e.g., children and adults; males and females; race/ethnic groups)

7) Administer the questionnaire, collect blood samples, and, if exposures are ongoing, collect home tap water or other appropriate environmental samples.

8) Analyze data from step 6 to do the following.
    a) Determine PFAS blood level estimates and the uncertainty for those estimates for the community as a whole and for subgroups such as:
        - Groups considered at risk for higher exposures
        - Children and adults
        - Males and females
        - Race/ethnic groups (if relevant)
        - Persons in different economic strata
        - Different neighborhoods
        - Different drinking water sources
        - Other
    b) Using questionnaire data, water PFAS information, and serum PFAS levels from the targeted community exposure assessment, develop the best predictive multivariate model of serum PFAS levels. This model can assist in predicting serum PFAS levels for persons who have water PFAS measurements but have not had their blood tested.

Additional Considerations

Pilot sampling. A community may be particularly concerned about exposure and want to know the magnitude of their PFAS body burden right away. A preliminary or pilot investigation may be useful while the exposure assessment planning steps described above are ongoing. If so, based on known exposure sources and length of time exposed, select a small number of individuals (e.g., 30–50) thought to have the highest exposures. While not a statistically based sample, the results may provide rapid preliminary information on a subset of community members suspected to be in the upper range of serum PFAS levels. These results may inform the community-based sampling design.

NOTE: This pilot sample is not representative of the general community and, therefore, is not meant to be a substitute for the statistically based, community sample described above in the 7-step approach.

Exposure and health effects. The approaches described above are exposure assessments and not epidemiologic studies. A study may include a comparison group, an expanded health effects questionnaire, additional laboratory data relating to potential health effects and, potentially, a medical records review. However, biomonitoring results from the community exposure assessment may be compared to biomonitoring results in exposure/health effects studies done in other population groups.

[3] The approach described in the NCEH/ATSDR PEATT is appropriate for exposure assessment of a general population with known or suspected exposure. Oversampling of subgroups that can be accomplished by simple stratification is also included. However, for some subgroups of interest, such as children or pregnant women, consider more complex statistical sampling approaches designed to measure blood PFAS exposure levels of a targeted population of interest.

CDC and ATSDR role. If requested, CDC and ATSDR will provide technical assistance to health departments to develop and execute this exposure assessment approach.

Answers to Commonly Asked Question about PFAS and Biomonitoring

- A scientifically designed community investigation allows for an assessment of the community's exposure profile in a timely manner (e.g., typically less than about two years for the community report, depending on logistics, funding, etc.). This includes information about high and low exposure estimates, PFAS levels in groups of special concern (e.g., children), and how personal factors such as drinking water source, length of residence, age, and occupation may affect results.
- The information derived from this approach can potentially be used to design a health study to monitor for possible health effects in these groups, even if not all of the individuals within these groups participated in biomonitoring.

What advice can be given to individuals who were not selected for biomonitoring?

- Whether selected or not for biomonitoring, individuals should take practical steps to reduce current exposure to PFAS. For example, use alternative water sources if advised by the local health officials.
- The community biomonitoring report should provide information about the range of serum PFAS levels and may provide information on how the levels vary among different population groups in the community. From these data, people who were not tested should be able to get an estimate of their likely serum PFAS level.
- If for some reason an individual still desires personal serum PFAS results, they should be encouraged to seek advice from their health care provider and other professionals (e.g., regional Pediatric Environmental Health Specialty Units or PEHSUs).[5]

How can individual serum PFAS concentrations be interpreted?

Serum PFAS concentrations for individuals 12 years of age and older can be compared to U.S. population results from CDC's National Health and Nutrition Examination Survey (NHANES). Serum PFAS have been measured in NHANES since 1999. As part of the ongoing NHANES, serum PFAS are measured in a one third sample of participants, ages 12 and older. Population-based reference values are available by age group (12-19 years, 20+ years), sex, and race/ethnicity (non-Hispanic black, non-Hispanic white, Mexican American). Beginning in 2011, the racial/ethnic groups of Asian (e.g., non-Hispanic Asian) and all Hispanics were added. The most recent survey results (2011-2014) are included in Appendix A.

Typically, the 95th percentile is used as the upper end of the reference range for the U.S. population. For children younger than 12 years, no national reference values exist.[6]

Biomonitoring sampling results cannot predict current or future health outcomes or diseases. That is, the results are not currently clinically actionable. Further, the biomonitoring results will not likely result in any different medical evaluations than just knowing or assuming that an individual was exposed to PFAS in contaminated drinking water above EPA health advisory levels in addition to other possible exposure sources (e.g., diet, occupation).There are no health-based screening levels for specific PFAS that clinicians can compare to the

[5]Clinical guidance for healthcare providers can be found at: http://www.atsdr.cdc.gov/pfc/index.html

[6]Some comparisons for children less than 12 years of age are available in the literature from studies in specific communities. These are not generalizable to other communities or the United States.

concentrations measured in blood samples. As a result, interpreting PFAS concentrations in individuals is limited in its use.

For More Information

For more information about PFAS, toxicity and exposure assessment, and clinical guidance for healthcare providers, visit the CDC/ATSDR PFAS web page: http://www.atsdr.cdc.gov/pfc/index.html

For more information about biomonitoring and PFAS reference ranges for the U.S. population since 2001, visit CDC's national biomonitoring program web page: http://www.cdc.gov/biomonitoring/ and the Exposure Report web page: https://www.cdc.gov/exposurereport/

PFAS Exposure Assessment Question Bank: Adults

This document provides a set of questions for state or local health departments to create a questionnaire for a Per- and Polyfluoroalkyl Substances (PFAS) exposure assessment of adults. Users can choose the type and order of questions from different sections listed below to create the questionnaire.

The question bank contains four sections:

- **Section A: Demographic Information**
- **Section B: Exposure Assessment**
- **Section C: Health Conditions**
- **Section D: Occupational History**

Each section has questions that are adapted from CDC's National Health and Nutrition Examination Survey (NHANES) and several other questionnaires used by state and local health departments for PFAS exposure assessments. State or local health departments can use this question bank to design questionnaires tailored to their communities' needs to assess PFAS exposures.

Section A: Demographic Information

This section provides sample questions to collect demographic information, as well as pregnancy and breastfeeding history information.

1. Unique ID: _ _ _ _ _ _ _ _ _
2. What is your name (Last, First, Middle Initial): _____ _____ ___
3. What is your date of birth (MM/DD/YYYY): _ _ / _ _ / _ _ _ _ □ Don't know □ Refused to answer
4. What is your sex: □ Male □ Female □ Other □ Refused to answer
5. What is your height: ____ (Feet) ____ (Inches) **or** ____ (cm) □ Don't know □ Refused to answer
6. What is your weight: ____ (Pounds) ____ (kg) □ Don't know □ Refused to answer
7. What is your address?
   Street_____ City _____ State _ _ Zip_ _ _ _ _ □ Refused to answer
8. Do you consider yourself to be Hispanic, Latino, or of Spanish origin?
   □Yes □No □ Don't know □ Refused to answer
9. Which one or more of the following would you say is your race? (Select all that apply)
   □ American Indian or Alaska Native □ Asian □ Black or African American
   □ Native Hawaiian or Other Pacific Islander □ White □ Don't know
   □ Refused to answer

Questions 10 to 15 are for Adult FEMALES ONLY.

10. Are you currently pregnant?
    □ Yes □ No □ Don't know □ Refused to answer □ Not Applicable
11. Have you been pregnant in the past from {*add number of years of interest*}?
    □ Yes □ No □ Don't know □ Refused to answer □ Not Applicable
12. If yes, please provide the number of pregnancies:
    ___ (number) □ Don't know □ Refused to answer □ Not Applicable
13. For each pregnancy, please provide the following information:

Number	Did this pregnancy result in live birth?(Y/N)	If yes, provide delivery date (MM/DD/YYYY):	Was child breastfed? (Y/N)	If yes, provide duration of breastfeeding (in months)

14. Have you completed menopause?
    □ Yes □ No □ Currently going through menopause □ Don't know
    □ Refused to answer □ Not Applicable
15. If yes, how old were you when completed menopause?
    ___ (years) □ Don't know □ Refused to answer □ Not Applicable
16. What is your annual household income?
    □ Less than $15,000 □ $15,000 to less than $25,000

- □ $25,000 to less than $35,000
- □ $35,000 to less than $50,000
- □ $50,000 to less than $75,000
- □ $75,000 or more
- □ Don't know
- □ Refused to answer

17. What is the highest grade or year of school you completed?
    - □ Never attended school
    - □ Grades 1 through 8 (Elementary)
    - □ Grade 9 through 11 (Some high school)
    - □ Grade 12 or GED (High school graduate)
    - □ Some college or technical school
    - □ College 4 years or more
    - □ Don't know
    - □ Refused to answer

Section B: Exposure Assessment

This section provides sample questions to assess exposure primarily through drinking water. However, additional questions on other potential exposure routes are also provided for investigators who want to assess exposures from these other potential routes.

1. How long have you lived at your home present in {*add affected/selected area here*}?
   __ (months) __ (years) □ Don't know □ Refused to answer

2. What is your current **main** source of drinking water in your home? (Select **one**)

   □ Public water system (City or County) Provide name: _____

   □ Private Well (**If selected, include questions 4 and 5 below**)

   □ Community well □ Bottled Water

   □ Don't Know □ Refused to answer

3. During the time you lived in a home served by the {*name of water system/private/community well*}, on average how many 8 oz cups of water or beverages prepared with tap water did you drink per day?
   ____ (8 oz cups) □ Didn't drink tap water □ Don't know □ Refused to answer

   Note: 1 cup = 8 oz; 2 cups = 1 pint (16 oz); 4 cups = 1 quart (32 oz); 16 cups = 1 Gallon (128 oz)

Questions 4 and 5 are for PRIVATE WELL owners only.

4. If you have a private well, has it been tested for PFAS?
   □ Yes □ No □ Don't know □ Refused to answer □ Not Applicable
5. If yes, do you know the date it was tested, who did the testing, and the results of the PFAS testing?

Date (MM/YYYY)	Private/Government laboratory	PFAS Results

6. Do you use water filters or treatment devices(s) for your tap water?
   □ Yes □ No □ Don't know □ Refused to answer □ Not Applicable
7. Which water filter or treatment device(s) are you currently using to filter or treat the tap water you drink? (Select all that apply)

   □ None, no filter or treatment device used □ None, use bottled water only

   □ Whole house carbon filter □ Under the sink carbon filter

   □ Faucet filter □ Pitcher filter

   □ Refrigerator filter □ Reverse osmosis (RO) system

   □ Other, specify: _____ □ Don't Know

   □ Refused to answer □ Not Applicable

Questions 8 through 12 are referring to the locations in the affected area/sampling frame only (show map or list of location if applicable). These questions can be used if the exposure assessment includes exposures other than or in addition to drinking water.

If area soil may be contaminated from past air contamination deposition from a nearby manufacturer, or by watering lawns, gardens, crops with contaminated water consider these potential exposure sources.

8. How frequently do you work or play in the soil (e.g. gardening, digging, farming, building, repairing, etc.) in {*insert affected area/sampling frame/locations*}? (Select one)

□ Once per month	□ A few times per year	□ Once per year
□ Rarely	□ Never	□ Don't know
□ Refused to answer		

9. If you work in the soil, at what address or place does this occur (list all locations)?

_____

_____

□ Refused to answer □ Not Applicable

10. How often do you eat "homegrown" or locally grown vegetables from {*insert affected area/sampling frame/locations*}? (Select one)

□ Several times per month	□ Few times per month	□ Once per month
□ A few times per year	□ Once per year	□ Rarely
□ Never	□ Don't know	□ Refused to answer

If area surface water bodies are contaminated and local fishing is possible:

11. How often do you eat fish locally caught from ponds, lakes, or rivers in {*insert affected area/sampling frame/locations*}? (Select one)

□ Several times per month	□ Few times per month	□ Once per month
□ A few times per year	□ Once per year	□ Rarely
□ Never	□ Don't know	□ Refused to answer

If livestock are raised in areas with soil contamination or if their drinking water source was contaminated:

12. How often you consume milk from animals raised on farms within {*insert sampling/affected area/location or list of affected farms*}?

□ Several times per month	□ Few times per month	□ Once per month
□ A few times per year	□ Once per year	□ Rarely
□ Never	□ Don't know	□ Refused to answer

Section C: Health Conditions

This section provides sample question to collect information related to past and/or existing health conditions or diseases. Investigators can create an open-ended question to collect information on past and/or existing health condition or diseases by organ system or they create a list of specific health effects based on their community concerns or past research. A list of potential PFAS-associated adverse health conditions or diseases studied in the existing literature is also provided in Appendix A.

1. Please provide information about all health conditions or disease you were diagnosed with in the {*add number of years of interest*} by your doctor:

Organ System	Condition (add additional rows as needed)	Year diagnosed
Cardiovascular	*{Health condition or disease}*	
Endocrine (hormonal)	*{Health condition or disease}*	
Gastrointestinal	*{Health condition or disease}*	
Integumentary (dermal)	*{Health condition or disease}*	
Lymphatic	*{Health condition or disease}*	
Muscular	*{Health condition or disease}*	
Neurologic	*{Health condition or disease}*	
Reproductive	*{Health condition or disease}*	
Skeletal	*{Health condition or disease}*	
Urinary	*{Health condition or disease}*	
Other	*{Health condition or disease}*	

Section D: Occupational History

This section provides sample questions to collect information about participant's occupational history.

1. Have you been employed in the last 20 years?
   □Yes □No (**If selected, SKIP this section**) □ Don't know □ Refused to answer

2. Is your current or past workplace in {*add number of years of interest*} located in the {*specify affected area or area of interest*}? (Use of a map to help identify if school/daycare located in the affected area or area of interest)
   □Yes □No □ Don't know □ Refused to answer

3. How long have you worked at your current/previous {*add duration based on exposure e.g., 1 yr or 5 yr etc.*} workplace present in {*add affected/selected area here*}?
   ___ (months) ___ (years) □ Don't know □ Refused to answer

4. What is/was the <u>main</u> source of drinking water you used at your workplace? (Select **one**)

   □ Public water system (City or County) Provide name: _____

   □ Private Well □ Community well

   □ Bottled Water □ Don't Know

   □ Refused to answer

5. During the time you worked at a workplace served by the {*name of water system/private/community well*}, on average how many 8 oz cups of water or beverages prepared with tap water did you drink per day?
   ____ (8 oz cups) □ Didn't drink tap water □ Don't know □ Refused to answer
   Note: 1 cup = 8 oz; 2 cups = 1 pint (16 oz); 4 cups = 1 quart (32 oz); 16 cups = 1 Gallon (128 oz)

NOTE: Due to their unique physical and chemical properties, PFAS are used in a variety of industrial applications and consumer products. PFAS have been used to provide non-stick surfaces on cookware and waterproof coatings for textiles and paper products. They serve as high performance surfactants in numerous products that must flow freely, including paints, cleaning products, fire-fighting foams used to fight fuel-based fires, and engineering coatings used in semiconductor production [1].

Beyond these uses, PFAS have been employed in hundreds of other applications across almost all industrial sectors, some of which are highlighted in Table 1. This questionnaire is not meant to be a comprehensive list of questions about all possible and relevant PFAS exposure sources. Environmental and occupational exposures can differ greatly among communities and public health officials choosing to conduct PFAS biomonitoring activities may need to consider adding questions regarding other sources of possible PFAS exposure.

6. Did you in the last {*add duration based on exposure e.g., 1 yr or 5 yr*} work at any of the following industries?
   □ Manufacturing of nonstick cookware such as Teflon® coated pots/pans
   □ Manufacturing of stain resistant coatings (e.g. Scotchguard®) used on carpets, upholstery, and other fabrics
   □ Manufacturing of water resistant clothing (e.g. Gore-Tex®)
   □ Never worked in the industries listed above

7. Were/Are you a firefighter {*add duration based on exposure e.g., 1 yr or 5 yr etc.*}?
   □Yes □No □ Don't know □ Refused to answer

8. If you worked in any of the industries listed in question 6 (also see Table 1 for detail list of industries) or was/is a firefighter, please provide your job title, brief job description, and duration of your work.

Company Name	Job Title	Brief Job Description	Year Started	Year Ended

Table 1. Common Uses of PFAS

Consumer Products	**Industrial Uses**
Cookware (Teflon®, Nonstick)	Photo-Imaging
Fast Food Containers	Metal Plating
Candy Wrappers	Semiconductor Coatings
Microwave Popcorn Bags	Aviation Hydraulic Fluids
Personal Care Products (Shampoo, Dental Floss)	Medical Devices
Cosmetics (Nail Polish, Eye Makeup)	Fire-Fighting Foam
Paints and Varnishes	Insect Baits
Stain Resistant Carpet	Printer and Copy Machine Parts
Stain Resistant Chemicals (Scotchguard®)	Chemically Driven Oil Production
Water Resistant Apparel (Gore-Tex®)	Textiles, Upholstery, Apparel and Carpets
Cleaning Products	Paper and Packaging
Electronics	Rubber and Plastics